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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/009,383      | 03/04/2002  | Maria Laura Gennaro  | 20869-8             | 7070             |

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PATENT DOCKET ADMINISTRATOR  
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ROSELAND, NJ 07068

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| EXAMINER |
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SWARTZ, RODNEY P

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| ART UNIT | PAPER NUMBER |
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1645

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| MAIL DATE | DELIVERY MODE |
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01/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |  |   |  |
|------------------------------|--|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/009,383       | <b>Applicant(s)</b><br>GENNARO, MARIA LAURA |  |
|                              | <b>Examiner</b><br>Rodney P. Swartz, Ph.D. | <b>Art Unit</b><br>1645                     |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 October 2007 has been entered.

Claims 1 and 35 have been canceled. Claims 3 and 9 have been amended.

2. Claims 2-10 are pending and under consideration.

### **Rejections Moot/Withdrawn**

3. The rejection of claims 1 and 35 under 35 U.S.C. 103(a) as being unpatentable over Reed et al (WO98/16645, 23 April 1998), is moot in light of the cancelation of the claims.

4. The rejection of claims 1 and 35 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancelation of the claims.

5. The rejection of claims 2-10 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn.

Applicant argues that the examiner has mischaracterized the statements made in the August 7, 2007 response by applicant, and that the statement actually states that the genome of *M. bovis* encodes MTBN4 and that the strain of BCG does not encode MTBN4. Thus, it is likely that one of skill in the art would mistakenly assume that the strain of BCG would encode MTBN4 and therefore, the rejection should be withdrawn.

The examiner has considered applicant's argument concerning the indefiniteness, and finds it persuasive.

### Rejections Maintained

6. The rejection of claims 2-10 under 35 U.S.C. 103(a) as being unpatentable over Reed et al (WO98/16645, 23 April 1998), is maintained.

Applicant argues that the examiner has mischaracterized the statements made in the August 7, 2007 response by applicant, and that the statement actually states that the genome of *M. bovis* encodes MTBN4 and that the strain of BCG does not encode MTBN4. Thus, it is likely that one of skill in the art would mistakenly assume that the strain of BCG would encode MTBN4 and therefore, the rejection should be withdrawn.

The examiner thanks applicant for clearing up the issue concerning applicant's prior statement of record.

However, the rejection is maintained for the following reasons.

Claim 2 is drawn to a product, i.e., "An isolated DNA molecule consisting of a DNA sequence encoding a segment of polypeptide MTBN4 shorter than full-length polypeptide MTBN4."

Instant polypeptide MTBN4 is SEQ ID NO:4. A sequence search for SEQ ID NO:4 indicates that sequence is identical to SEQ ID NO:110 of WO98/16645. Reed et al not only teach the amino acid sequence of MTBN4, but also teach an isolated DNA comprising the DNA sequence encoding the polypeptide, i.e, a fragment of SEQ. ID. No:109 and probes which identify the DNA sequence, thus are less than full length DNA which would encode less than full length protein (Example 3, page 38, lines 22-27). Given that the protein sequence was known, one of ordinary skill in the art would instantly envision a polynucleotide sequence consisting of a DNA encoding said sequence and that said DNA sequence is obvious. Furthermore, it would have been obvious to one of ordinary skill in the art to place the sequence into a vector,

transform a host cell with that vector, and to admix said vector with a pharmaceutically acceptable diluent or filler as taught by Reed et al for the other DNA sequences in the document (page 39, line 18 to page 45, line 1; claims 5-8, 40-47).


### **Conclusion**

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER

Art Unit 1645

January 2, 2008